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BEFORE THE BOARD OF PATENT APPEALS AND INTERFERENCES

Paper No. 03242011

Application Number: 10/600,027
Filing Date: June 19, 2003
Appellant(s): Odrich, Mark et al

Michael T. Rosato
For Appellant

EXAMINER'S ANSWER

This is in response to the appeal brief filed December 30, 2010.

(1) Real Party in Interest

The examiner has no comment on the statement, or lack of statement, identifying by name the real party in interest in the brief.

(2) Related Appeals and Interferences

The following are the related appeals, interferences, and judicial proceedings known to the examiner which may be related to, directly affect or be directly affected by or have a bearing on the Board's decision in the pending appeal:

Appeal No. 2008001260 (BPAI, 2008), prior decision on the instant case (10/600,027)

(3) Status of Claims

The following is a list of claims that are rejected and pending in the application: claims 1-9 and 16-22.

(4) Status of Amendments After Final

The examiner has no comment on the appellant's statement of the status of amendments after final rejection contained in the brief.

(5) Summary of Claimed Subject Matter

The examiner has no comment on the summary of claimed subject matter contained in the brief.

(6) Grounds of Rejection to be Reviewed on Appeal

The examiner has no comment on the appellant's statement of the grounds of rejection to be reviewed on appeal. Every ground of rejection set forth in the Office action from which the appeal is taken (as modified by any advisory actions) is being maintained by the examiner except for the grounds of rejection (if any) listed under the subheading "WITHDRAWN REJECTIONS." New grounds of rejection (if any) are provided under the subheading "NEW GROUNDS OF REJECTION.

(7) Claims Appendix

The examiner has no comment on the copy of the appealed claims contained in the Appendix to the appellant's brief.

(8) Listing of Evidence Relied Upon

The following is a listing of the prior art of evidence (e.g. patents, publications Official Notice, and admitted prior art) relied upon in the rejection of claims under appeal.

Number (Title)	Name	Date
6,312,414	Largent	November 6, 2001
6,027,494	Frey	February 22, 2000

(9) Grounds of Rejection

The following ground(s) of rejection are applicable to the appealed claims:

Claims 1-9 and 16 are rejected under 35 U.S.C. 103(a) as being unpatentable over Frey in combination with Largent. Frey teaches a laser surgical system including a laser and a processor and scaling the ablation to the pupil size (see column 1, lines 5-10 and column 2, lines 46-55). Largent teaches designing a corneal ablation to include multiple zones of ablation (see column 4, lines 23-43) that can include both near and far vision corrections (see column 1, lines 17-24), which would mitigate presbyopia. It would have been obvious to the artisan of ordinary skill to employ the device of Frey on a subject with presbyopia, since this condition is correctable with laser sculpture as taught by Largent, or to employ the pupil scaling device of Frey in the presbyopia treating system of Largent, since this would reduce the halo effect and improve night vision, as taught by Frey, thus producing a method such as claimed.

Claims 17-22 are rejected under 35 U.S.C. 103(a) as being unpatentable over Frey in combination with Largent. Frey teaches a laser surgical system including a laser and a processor and scaling the ablation to the pupil size (see column 1, lines 5-10 and column 2, lines 46-55). Largent teaches designing a corneal ablation to include multiple zones of ablation (see column 4, lines 23-43) that can include both near and far vision corrections (see column 1, lines 17-24), which would mitigate presbyopia. It would have been obvious to the artisan of ordinary skill to employ the device of Frey on a subject with presbyopia, since this condition is correctable with laser sculpture as taught by Largent, or to employ the pupil scaling device of Frey in the presbyopia treating system of Largent, since this would reduce the halo effect and improve night vision, as taught by Frey, thus producing a device such as claimed.

(10) Response to Argument

Concerning the rejections, appellants argue that the examiner has not established a prima facie case of obviousness because, the references "fail to teach or suggest adjusting **multiple** regions of an ablation profile…based on an individual patient's pupil size" (see the instant Brief, the third sentence of the first full paragraph on page 6, emphasis in original), and because the examiner's reliance on the previous Board of Appeals decision is misplaced, due to the instant claims being different from those for which the obviousness rejection was upheld in the previous Board Decision. The examiner must respectfully disagree, as will be set forth more full below.

The Appealed Claims Are Obvious Over The Combination Of Frey And Largent In View Of The Knowledge Of One Of Ordinary Skill In The Art

Claims 1-9 and 16

Firstly appellants argue that Frey only teaches the manipulation of the outer boundary of an ablation profile based on pupil size and does not discuss multiple zones of correction. While Largent, appellants argue, is merely directed to providing a multifocal ablation profile made up of concentric annular zones of varying refractive power, with no teaching of variation of any aspect of the ablation profile with relation to pupil size. Then appellants conclude that neither "reference teaches a relationship between pupil size and inner **or** multiple regions of an ablation profile" and even if "such an adjustment were **attempted** based on the combined references, neither reference provides any guidance adjusting multiple regions of an ablation profile based on pupil size" (see the instant Brief, the last two sentences of the first full paragraph on page 7,

emphasis in original). And appellants go on to assert, via a footnote, that "the lack of any identified/recognized relationship between inner/multiple ablation regions and pupil size would defeat a rational for such a proposed modification (see the instant Brief, footnote numbered 2 on page 7).

The examiner must take issue with these assertions by appellants. Firstly, they are based on the premise of complete ignorance of one of ordinary skill in the art, with regards to any desirable ratio of the various corrections (e.g. near- and far- vision) to one another. As set forth in the previous examiner's answer, this premise is not only unrealistic, but directly contradicted by the Largent reference:

> In the discussion of the various teachings of Frey and Largent, appellant describes the teachings of Largent as a "one size fits all" outer ablation shape (see the instant Brief, page 10, second sentence of the final paragraph). However, Largent discusses no particular size at all, nor does Largent anywhere mention that the outermost ablation diameter must be given size, or even a range of sizes. Thus it is unclear from whence appellant has determined this description of Largent, as it does not appear to derive from the Largent reference.
>
> Appellant then argues that one of ordinary skill in the art would not understand the necessity of providing useful corrections for all the distance corrections ablated into the cornea, arguing that the examiner's analogy to the adjustment of spectacle lenses is flawed. The examiner must respectfully note that Largent specifically states that "[T]the specific configuration of the power curve across the cornea can be tailored to suit the needs of the patient and the particular design considerations" (see column 1, lines 57 to 59), (sic, 59).) Thus clearly adjustment of all the curvature zones is contemplated in the disclosure of Largent, and is so well known to one of ordinary skill in the art that not even one example of how this would be accomplished is given. Given that claim 1 of Largent recites a "method of vision correction comprising … directing the modulated laser beam to the cornea of a patient to ablate a region of the cornea to different degrees to provide the cornea with different progressive vision correction powers" and given the Largent is an issued U.S. Patent, the presumption of validity which Largent is due requires the assumption that the tailoring "to suit the needs of the patient", so as to provide a "method of vision correction" as claimed, one must conclude that one of ordinary skill in the art is quite capable of providing the ratios of the various curvature regions, especially in view of the fact that Largent supplies no ratios at all.

(see the examiner's answer mailed February 26, 2007, beginning with the second full sentence on page 7, through the sentence bridging pages 7 and 8). Thus there is ample evidence of record that the determination of the ratios of the various zones was well within the scope of one of ordinary skill in the art at the time of the invention, thus, when the overall ablation zone size is changed, the sizes of all correction zones would also be changed "to suit the needs of the patient" as specifically disclosed by Largent.

At pages 7 and 8 of the instant Brief, appellants summarize the teachings of Frey and Largent. Proceeding to page 9, appellants again make the argument that only the combination of the two references would only teach one of ordinary skill in the art to modify the outer boundary of the entire ablation, maintaining the position of all the inner boundaries. However, as pointed out by the examiner in the final rejection mailed February 23, 2006 (see the paragraph bridging pages 2 and 3 thereof, emphasis in original):

> "prima facie obviousness is evaluated on the basis of what the combined references teach one of ordinary **skill** in the art at the time of the invention. The examiner notes that one having ordinary skill in the art would be an ophthalmologist who is at least familiar with the basics of providing multifocal correction to patents afflicted with presbyopia. Those familiar with the basics will understand that both corrections are provided for a reason and that both corrections must be usefully available to the patient in order to produce a useful correction e.g. in the method of Largent. The same knowledge that would allow the ophthalmologist to determine the relative ratios of the two corrections to begin with, would allow the same ophthalmologist to produce an appropriate ratio of the relative areas of the two corrections in view of an alteration in size of the optical zone based on pupil size, as taught by Frey et al. Just as if the ophthalmologist were adjusting a prescription for bifocals form (sic, from) one size lens to a second, different size lens in a pair of conventional spectacles."

And as pointed also out by the examiner in the final rejection mailed May 28, 2010 (see the paragraph bridging pages 7 and 8 thereof):

> It is clear that the arguments set forth in the instant response are equivalent to those argued in the Brief on Appeal. In responding, the Board particularly noted that "As pointed out above, the Supreme Court recently noted that the analysis under 35 U.S.C. 5 103 "need not seek out precise teachings directed to the specific subject matter of the challenged claim, for a court can take account of the inferences and creative steps that a person of ordinary skill in the art would employ." KSR Int'l Co. v. Teleflex Inc., 127 S. Ct. 1727, 1741 (2007). In the instant case, we agree with the Examiner that one of ordinary skill in the art using Frey's system, being a person of ordinary creativity and common sense, KSR, 127 S. Ct. at 1742-43, would have reasonably inferred from Largent that it was desirable to reshape Frey's pupil-sized corneal optical zone into separate regions that corrected for both near and far vision, in patients requiring those vision corrections." Essentially, the reference to Largent discusses no particular ratios of the various near and far vision zones, thus the proper proportion of the area of the near vision zone to the far vision zone must have been part of the knowledge of one of ordinary skill in the art at the time of the invention of Largent. Otherwise, according to applicant's scenario of the actions of one of ordinary skill in the art, one of ordinary skill in the art would allow, in the event that the patient had a very small pupil diameter under fully dilated conditions, the outer annular correction to be completely eliminated, leaving only the monofocal correction of the inner area to treat the presbyopic eye. Clearly one of ordinary skill in the art, seeking to treat presbyopia with a multifocal ablation would never do this.

Further given that Largent includes many ablation zone, and not just two, it is conceivable that a patient with a small pupil size, using appellants' theory regarding the manner in which one of ordinary skill in the art would combine Frey and Largent, would have several of the ablation zones of Largent omitted entirely. However, appellant has never fully explained the manner in which one of ordinary skill in the art would consider such a truncated ablation profile "tailored to suit the needs of the patient" as required by Largent (see column 1, line 58).

Proceeding, appellants then assert that "it does not appear that combining Frey/Largent to produce the claimed invention would be **technically feasible** without guidance of the present application, neither reference provides any teachings of **how** adjustments to the multiple regions might be accomplished, even if attempted" (see the instant Brief, the first two sentences on page

10, emphasis in original). However, as set forth above, it is the examiner's view that the same knowledge that allowed one of ordinary skill in the art, an ophthalmic surgeon, familiar with at least the basics of providing multifocal corrections to patients with presbyopia, to determine the relative ratios of the two corrections to begin with, would allow the same ophthalmologist to produce an appropriate ratio of the relative areas of the two corrections in view of an alteration in size of the optical zone. Thus the knowledge of the desirable ratio or range of ratios for these near- and far- vision zones when providing multifocal ablations was clearly within the scope of one of ordinary skill in the art at the time of the invention.

Thus the argued limitations of claim 1: "...adjusting an ablation cut profile of the multifocal ablation shape in response to the size of the pupil so as to provide a balance of near vision correction provided by the first region and far vision correction provided by the second region for the patient..."; claim 16: "...adjusting an ablation cut profile for both the first region and second region of the multifocal ablation shape in response to the size of the pupil so as to provide a balance of near vision correction provided by the first region and far vision correction provided by the second region for the patient..." (emphasis in original); and claim 17: "...determining the distribution of laser beam pulses to ablate the first and second regions of the multifocal ablation shape, where the distribution of laser beam pulses for ablating both the first and second regions are determined in response to the size of the pupil so as to provide a balance of near vision correction provided by the first region and far vision correction provided by the second region for the patient" (emphasis in original), are reasonably conveyed to one of ordinary skill in the art by the applied combination, to produce the well desired ratio of near vision to far vision correction "to suit the needs of the patient" as specifically taught by Largent at column 1,

line 58. It should be noted that Largent contemplate both scanning the laser and modulating the laser energy to produce the multifocal ablation (see Largent column 2, lines 24-28 and the Decision FF 11), while modulating is preferred scanning is also disclosed. In any event, however, both of these modalities are encompassed by appellants' term "distribution" as used in claim 17. This can be seen from lines 13- on page 15 of the originally filed disclosure (paragraph [0063] of the Pre-Grant Publication): "Other techniques besides the above area profiling of a laser beam may be used to profile the laser beam to a **desired size and energy distribution** on the surface of the eye. For example a lens may be used to profile a beam exiting from an aperture by focusing the beam to a suitably small area and desired energy profile as described in U.S. Pat. No. 4,718,418, the full disclosure of which is herein incorporated by reference. Also a diffractive optic may be used to adjust an energy profile of the laser beam on the surface of the eye" (emphasis added). And as also can be seen from the foregoing (by the citation of U. S. Patent No. 4,718,418), the devices which provide such distribution and the method of doing so are well known in the art.

Regarding The Prior Decisions By The Board Of Appeals

Here appellants assert that the claims at bar are of differing scope than those upon which the Decision rendered May 21, 2008 (hereinafter "the Decision) was based. The examiner has never disputed this, however, the examiner is of the belief that the differences that do exist between the two claims are of little patentable moment, when viewed in light of the combined

teachings of Frey and Largent as read by one of ordinary skill in the art at the time of the invention.

Prior Board Decisions And Comparison Of Current Claims

Firstly, regarding claims 1-9, appellants note that the Board did not extend the rejection then applied to claims 10-15, to claims 1-9, which were also pending in the case. However, on reviewing the claims, the examiner came to the realization that the meaning attributed to the "adjusting" step in claim 1, which derived from the paragraph bridging pages 5 and 6 of the originally filed disclosure (paragraph [0022] of the Pre-Grant Publication), was incorrect, or at least too narrow, as requiring the adjustment be made taking into account corneal healing, as the record clearly reflects. However, a careful reading of the originally filed disclosure, reveals that this adjusting is independent from the maximum size of the pupil, or at the very least, not the only way the ablation can be adjusted to take into account maximum pupil size.

Even assuming that the taking account of the corneal healing were inherently required by the term "adjusting" as used in the claims, this would still not render them patentable. In reversing the examiner's written description rejection, the Board explicitly stated that taking corneal healing into account was something that was within the scope of one of ordinary skill in the art (see the Decision, attached, the first full paragraph on page 10). This being within the ability of one of ordinary skill in the art to do, and given that the best correction possible is desired to be produced for the patient, one of ordinary skill in the art, an ophthalmologist who is at least familiar with the basics of providing multifocal correction to patents afflicted with

presbyopia, would seek to take the changes to the ablation shape produced during the surgery that result from the healing of the cornea into account, thus to provide a final corneal shape which is "tailored to suit the needs of the patient" as required by Largent.

Then appellants provide side by side comparisons of claim 10 (now cancelled) and claim 17 (pending) as well as claims 1 and 16 (both pending) to highlight the differences therein.

Examiner's Reopening Of Prosecution Of The Current Rejections

Firstly, appellants assert the Decision did not change the scope of the claims. This is absolutely true. However, the Decision did enlighten the examiner is to the true breadth of the subject matter claimed in claim 1. The fact is that the examiner had read the claim to narrowly, and realized this when reviewing the Decision. This lead the examiner to realize that the art rejection which was applied to claims 10-15 was equally applicable to claims 1-9.

Secondly, appellants argue that claims 1-9 were already reviewed for obviousness during the original prosecution. This is also true. However, the examiner, having since properly construed claims 1-9 using the broadest reasonable interpretation of the terms therein (as discussed in the first paragraph of the section labeled **Prior Board Decisions And Comparison Of Current Claims**), in continuing the obviousness inquiry, the examiner determined these claims to be obvious (as discussed in the first and second paragraphs of the section labeled **Prior Board Decisions And Comparison Of Current Claims**)

Continuing appellants assert that "it is believed that the issue of potential obviousness of claims 1-9 in view of Frey and Largent has already been considered by the Board Per

MPEP§1213.02 and 37 C.F.R. 41.50. (see the instant Brief, the paragraph bridging pages 15 and 16). However, MPEP§1213.02 makes it clear that:

> "While ** the Board >is authorized< to reject allowed claims, this authorization is not intended as an instruction to the Board to examine every allowed claim in every appealed application. It is, rather, intended to give the Board express authority to act when it becomes apparent, during the consideration of rejected claims, that one or more allowed claims may be subject to rejection on either the same or on different grounds from those applied against the rejected claims. Since the exercise of authority under 37 CFR *>41.50(b)< is discretionary, no inference should be drawn from a failure to exercise that discretion.

See the penultimate paragraph of MPEP However, MPEP§1213.02 makes it clear that1313.02. While appellants' have attempted to draw such an inference, this does not rebut the prima facie showing of obviousness set forth above with regards to the claims.

Next appellants assert that "the Board's affirming of the obviousness rejection of prior claim 10 (now canceled) over Frey/Largent does not necessarily support a corresponding rejection of the **differently defined** invention of claims 1-9 and 16-22" (see the instant Brief, the first sentence of the first full paragraph on page 16, emphasis and parenthetical comments in original). The examiner agrees, the language of claim 17 being different from that of canceled claim 10, the Decision regarding claim 10 does not necessarily apply. However, neither does this necessarily imply that the rejections are no longer applicable. The examiner believes they are, as set forth more fully above.

Lastly, appellants argue that the limitation drawn to adjusting multiple regions (as opposed to merely "balancing" them as required by claim 10 (it is noted that claim 17 recites "balancing" the regions as well), would not have been obvious to one of ordinary skill in the art, as argued in the instant Brief. However, this argument is not convincing in view of the lack of

any specific disclosure in Largent to provide any specific ratio of the various regions, which clearly shows that this knowledge was in possession of one of ordinary skill in the art, particularly in light of the disclosure therein that "specific configuration of the power curve across the cornea can be tailored to suit the needs of the patient" (see column 1, lines 57-58) and in light of the express claiming therein of providing the multifocal ablation for the purpose of "vision correction" (see e.g. claim 1). It is unclear why appellants have determined that one of ordinary skill in the art would utterly disregard the desire to craft a curvature profile "tailored to suit the needs of the patient" then cut parts off on the basis of the maximum pupil size dictated by the device and method of Frey. Much more likely, one of ordinary skill in the art, an ophthalmic surgeon, familiar with the basics of providing multifocal corrections to patients with presbyopia, would use common sense, as set forth in KSR International Co. v Teleflex Inc. 82 USPQ2d 1385 (Supreme Court, 2007) and first determine the maximum useful extent of the recurvature (which is related to the maximum pupil diameter), and then craft a curvature profile "tailored to suit the needs of the patient". As appellants have thus far in the prosecution of the instant application failed to produce one argument as to why one of ordinary skill in the art, using common sense, would not behave this way, and as set forth in the Decision (see page 19, the two full paragraphs):

> "As pointed out above, the Supreme Court recently noted that the analysis under 35 U.S.C. 103 "need not seek out precise teachings directed to the specific subject matter of the challenged claim, for a court can take account of the inferences and creative steps that a person of ordinary skill in the art would employ." KSR Int'l Co. v. TeleFlex Inc., 127 S. Ct. 1727, 1741 (2007).
>
> In the instant case, we agree with the Examiner that **one of ordinary skill in the art using Frey's system, being a person of ordinary creativity and common sense, KSR, 127 S. Ct. at 1742-43, would have reasonably inferred from Largent that it was desirable to reshape Frey's pupil-sized corneal optical zone into separate regions that corrected for both near and far vision,**

in patients requiring those vision corrections. Because failing to include both of Largent's reshaped corrective regions within Frey's pupil-sized optical zone would have defeated the purpose of Largent's multifocal correction, we agree with the Examiner that one of ordinary skill using Frey's system would have been prompted to modify the system with instructions directing the processor to determine the multifocal correction based on the optimal pupil-sized operative zone."

Thus, despite the added limitation of claim 17 as contrasted with canceled claim 10, the combination discussed in the Decision still reads on the claims. This is because, on following the teachings of Largent would first want to determine the area to be ablated (i.e. the corneal area corresponding to the maximum pupil dilation) before establishing the curvature profile "tailored to suit the needs of the patient" as taught by Largent, which would include employing the knowledge of one of ordinary skill in the art in determining the ratio of the area of far vision correction compared to near vision correction, which would necessarily require determining the relative boundaries thereof. Further, as set forth above, appellants have provided no showing that the relative amounts of these two corrections were just picked at random by one of ordinary skill in the art at the time of the invention. Thus the determination of this must be within the scope of one of ordinary skill in the art, as evidenced by the teachings and claims of Largent, as also set forth above.

(11) Related Proceedings Appendix

See appendix

(12) Conclusion

It is the examiner's firm opinion that the appealed claims are not patentable for the reasons argued above. Appellant has presented no convincing argument as to why the rejections

set forth above are not obvious or proper. Therefore, it is respectfully submitted that the final rejection be affirmed

Respectfully submitted,

/david shay/
Primary Examiner, Art Unit 3769

David Shay
March 28, 2011

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